APR 2 3 2002

K021051

Summary of Safety and Effectiveness
per SMDA 1990 and 21 CFR 807.92
AnnuloFlo® Annuloplasty System

Submitter: Sulzer Carbomedics, Inc.
1300 East Anderson Lane
Austin, Texas 78752
U.S.A.

Contact: Teffany Hankinson
Regulatory Affairs Associate
Telephone: (512) 435-3202
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Date of Summary: March 27, 2002

Classification Name: Annuloplasty Ring

Common Name: Annuloplasty Ring

Proprietary Name: AnnuloFlo® System

Predicate Device: AnnuloFlex™ Annuloplasty System

Statement of Intended Use: The AnnuloFlo® System is intended for use in the repair of the human cardiac valve.

Statement of Indications for Use: The AnnuloFlo® annuloplasty ring is indicated as a reinforcement for repair of the human cardiac mitral valve damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

Description of Device: The AnnuloFlo® System consists of an annuloplasty ring, and a complete set of instrumentation provided in a tray to properly size the annulus and implant the annuloplasty ring. The annuloplasty ring is designed to reinforce the native annulus while retaining the native valve apparatus.

The AnnuloFlo® annuloplasty ring employs materials with a long and satisfactory history of use in cardiovascular applications. All materials are non-ferrous, have extensive history in implants and do not present a significant risk during Magnetic Resonance Imaging (MRI). The annuloplasty ring consists of a titanium stiffener ring enclosed in a sewing ring of silicone and knitted polyester fabric.

The mitral AnnuloFlo® annuloplasty ring is kidney shaped. The curved posterior segment of the ring corresponds to the native posterior leaflet. The open segment of the ring corresponds to the anterior leaflet.

Technological Comparison: The sewing cuff material of the AnnuloFlo® annuloplasty ring is similar to the sewing cuff material used in the AnnuloFlex™ annuloplasty ring.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2002

Sulzer Carbomedics, Inc.
c/o Teffany Hankinson
Regulatory Affairs Associate
1300 East Anderson Lane
Austin, TX 78752

Re: K021051
Trade/Device Name: AnnuloFlo® System, Mitral AR-700
sizes 26, 28, 30, 32, 34, and 36 mm
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II
Product Code: KRH
Dated: March 28, 2002
Received: April 1, 2002

Dear Ms. Hankinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K970375

Device Name: AnnuloFlo® System

Indications for Use: The AnnuloFlo® annuloplasty ring is indicated as a reinforcement for repair of the human cardiac mitral valve damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K970375